



AC-09-40

April 9, 2007

Roger Citron, R.Ph.
Montana Department of Public Health
and Human Services
1400 Broadway
P.O. Box 202951
Helena, MT 596202951

Dear Mr. Citron:

Our Senior NAE Representative, Elaine Zompolas, has referred your request for information regarding VYTORIN (ezetimibe/simvastatin). Your inquiry concerned the indications and/or contraindications for VYTORIN.

VYTORIN contains two lipid-lowering compounds: ezetimibe, a selective inhibitor of intestinal cholesterol absorption and simvastatin, a 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase inhibitor.

The indications for VYTORIN are listed below.

- *Primary Hypercholesterolemia*
VYTORIN is indicated as adjunctive therapy to diet for the reduction of elevated total-C, LDL-C, Apo B, TG, and non-HDL-C, and to increase HDL-C in patients with primary (heterozygous familial and non-familial) hypercholesterolemia or mixed hyperlipidemia.
- *Homozygous Familial Hypercholesterolemia (HoFH)*
VYTORIN is indicated for the reduction of elevated total-C and LDL-C in patients with homozygous familial hypercholesterolemia, as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or if such treatments are unavailable.

The contraindications for VYTORIN are listed below.

- Hypersensitivity to any component of this medication
- Active liver disease or unexplained persistent elevations in serum transaminases
- *Pregnancy and lactation.* Atherosclerosis is a chronic process and the discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Moreover, cholesterol and other products of the cholesterol biosynthesis pathway are essential components for fetal development, including synthesis of steroids and cell membranes. Because of the ability of inhibitors of HMG-CoA reductase such as simvastatin to decrease the synthesis of cholesterol and possibly other products of the cholesterol biosynthesis pathway, VYTORIN is contraindicated during pregnancy and in nursing mothers. **VYTORIN should be administered to women of childbearing age only when such patients are highly unlikely to conceive.** If the patient becomes pregnant while taking this drug, VYTORIN should be discontinued immediately and the patient should be apprised of the potential hazard to the fetus.

The above information is supplied to you as a professional service in response to your specific request. Merck/Schering-Plough Pharmaceuticals does not recommend the use of its products in any manner other than as described in the prescribing information. Enclosed for your convenience is prescribing information for VYTORIN.

Sincerely,

Ruth Stolz, MD

Ruth Stolz, M.D.
Director
Medical Services

Enclosure: Circulars